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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,016	04/01/2005	Mathias Bergman	014975-112	7816

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EXAMINER	
LUKTON, DAVID	
ART UNIT	PAPER NUMBER
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,016	BERGMAN ET AL.	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §131 and 132.

A CRF listing has been submitted. However, not all of the sequences have been accounted for. For example, a sequence listing has not been provided for either of the following (page 26, line 27+):

RQIKIWFQNRRMKWKK

KLAKLAK

Applicant is given the time period set in this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

✦

Pursuant to the directives of the amendment filed 4/1/05, claims 6, 10, 11, 18-22 have been amended, and claims 26-28 added. Claims 1-28 are now pending.

. . . .

Restriction to one of the following inventions is required under 35 U.S.C. §121:

1) Claims 1-9, 19, drawn to a compound that comprises the following formula:

$$Cy\text{-}Rr_n\text{-}Dd\text{-}Ee\text{-}Ff\text{-}Rr_m\text{-}Cyy$$

2) Claim 10, drawn to a compound that is obtained by derivatizing or activating or protecting a compound of the following formula:

$$Cy\text{-}Rr_n\text{-}Dd\text{-}Ee\text{-}Ff\text{-}Rr_m\text{-}Cyy$$

or the compound of the indicated formula which is bonded to a solid support.

3) Claims 11-18, 26, drawn to a conjugate of an "effector unit" and a compound of the following formula:

$$Cy\text{-}Rr_n\text{-}Dd\text{-}Ee\text{-}Ff\text{-}Rr_m\text{-}Cyy$$

4) Claims 20-22, drawn to a method of preparing a medicament.

5) Claims 23-25, drawn to a method of treating cancer by administering one of the Group 1 compounds/compositions.

6) Claim 27, drawn to a method of preparing a medicament.

7) Claim 28, drawn to a method for treating cancer.

The claimed inventions are distinct.

The first point is that claim 1 encompasses a considerable array of peptides, many of which are known. A small sampling of what is encompassed is provided by the following list:

CAIRSFC				
CGIRSFC	DLIRSFK	ETIRSFK	CESRIEC	DPSRINK
CDIRSFC	DMIRSFK	EVIRSFK	CFSRIGC	DQSRIPK
CEIRSFC	DNIRSFK	EWIRSFK	CHSRIHC	DRSRIQK
CFIRSFC	DPIRSFK	EYIRSFK	CKSRIIC	DSSRIRK
CHIRSFC	DQIRSFK	EAIRSAK	CLSRIKC	DTSRISK
CKIRSFC	DRIRSFK	EGIRSCK	CMSRILC	DVSRITK
CLIRSFC	DSIRSFK	EDIRSDK	CNSRIMC	DWSRIVK
CMIRSFC	DTIRSFK	EEIRSEK	CPSRINC	DYSRIWK
CNIRSFC	DVIRSFK	EFIRSGK	CQSRIPC	EASRIFK
CPIRSFC	DWIRSFK	EHIRSHK	CRSRIQC	EGSRIFK
CQIRSFC	DYIRSFK	EKIRSIK	CSSRIRC	EDSRIFK
CRIRSFC	DAIRSAK	ELIRSKK	CTSRISC	EESRIFK
CSIRSFC	DGIRSCK	EMIRSLK	CVSRITC	EFSRIFK
CTIRSFC	DDIRSDK	ENIRSMK	CWSRIVC	EHSRIFK
CVIRSFC	DEIRSEK	EPIRSNK	CYSRIWC	EKSRIFK
CWIRSFC	DFIRSGK	EQIRSPK	DASRIFK	ELSRIFK
CYIRSFC	DHIRSHK	ERIRSQK	DGSRIFK	EMSRIFK
CAIRSAC	DKIRSIK	ESIRSRK	DDSRIFK	ENSRIFK
CGIRSCC	DLIRSKK	ETIRSSK	DESRIFK	EPSRIFK
CDIRSDC	DMIRSLK	EVIRSTK	DFSRIFK	EQSRIFK
CEIRSEC	DNIRSMK	EWIRSVK	DHSRIFK	ERSRIFK
CFIRSGC	DPIRSNK	EYIRSWK	DKSRIFK	ESSRIFK
CHIRSHC	DQIRSPK	CASRIFC	DLSRIFK	ETSRIFK
CKIRSIC	DRIRSQK	CGSRIFC	DMSRIFK	EVSRIFK
CLIRSKC	DSIRSRK	CDSRIFC	DNSRIFK	EWSRIFK
CMIRSLC	DTIRSSK	CESRIFC	DPSRIFK	EYSRIFK
CNIRSMC	DVIRSTK	CFSRIFC	DQSRIFK	EASRIAK
CPIRSNC	DWIRSVK	CHSRIFC	DRSRIFK	EGSRICK
CQIRSPC	DYIRSWK	CKSRIFC	DSSRIFK	EDSRIDK
CRIRSQC	EAIRSFK	CLSRIFC	DTSRIFK	EESRIEK
CSIRSRC	EGIRSFK	CMSRIFC	DVSRIFK	EFSRIGK
CTIRSSC	EDIRSFK	CNSRIFC	DWSRIFK	EHSRIHK
CVIRSTC	EEIRSFK	CPSRIFC	DYSRIFK	EKSRIIK
CWIRSVC	EFIRSFK	CQSRIFC	DASRIAK	ELSRIKK
CYIRSWC	EHIRSFK	CRSRIFC	DGSRICK	EMSRILK
DAIRSFK	EKIRSFK	CSSRIFC	DDSRIDK	ENSRIMK
DGIRSFK	ELIRSFK	CTSRIFC	DESRIEK	EPSRINK
DDIRSFK	EMIRSFK	CVSRIFC	DFSRIGK	EQSRIPK
DEIRSFK	ENIRSFK	CWSRIFC	DHSRIHK	ERSRIQK
DFIRSFK	EPIRSFK	CYSRIFC	DKSRIIK	ESSRIRK
DHIRSFK	EQIRSFK	CASRIAC	DLSRIKK	ETSRISK
DKIRSFK	ERIRSFK	CGSRICC	DMSRILK	EVSRITK

The foregoing list, however, barely scratches the surface of what might be encompassed. The foregoing list only includes acyclic peptides in which "n" and "m" are both unity (i.e., equal to one); various other combinations of "n" and "m" are possible. In addition, cyclic variants would be included. In addition, even for the case where "n" and "m" are both unity, and wherein the compound consists of no more and no less than seven amino acids, the reality is that the C-terminal and N-terminal amino acid can vary without limit; for example, if the C-terminal and N-terminal amino acids are both glycine, bonding can occur in a "head to tail" fashion between the amino group of one glycine and the carboxyl group of the other. Further, peptides and proteins of any length are encompassed. The claimed invention does not "define a contribution" over the prior art.

Group 1 is distinguished from Group 2 in that the Group 1 compounds are any that comprise the formula Cy-Rr_n-Dd-Ee-Ff-Rr_m-Cyy, without limit, whereas, in the case of Group 2, the "unit" must be derivatized, activated, protected or solid support-bound. Similarly, Group 3 is distinguished in that this group requires coupling to an effector unit. Notwithstanding the foregoing, in the unlikely event that claim 1 were found to be allowable in its present form, rejoining of Groups 2 and 3 would take place. And in the event that Group 1 were elected, and claims therein found allowable in further limited form, it would become

appropriate to revisit the matter of restriction between Group 1 (on the one hand) and Groups 2-3 (on the other hand). For example, suppose that applicants were to choose to amend claim 1 to require that Bb represents canavanine, "m" is an integer of 1 and Cyy is cysteine; suppose further that such a genus were determined to be allowable. Under this hypothetical scenario, rejoining of Groups 2 and 3 would become likely at that point, subject of course to the same limitations on the subsequences permitted by claim 1.

Inventions 1 and 5 are related as product and process of use, as are Groups 3 and 7. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). However, in the event that Group 1 is elected, and claims therein found allowable, the corresponding method-of-use claims will be rejoined for further examination. Similarly, in the event that Group 3 is elected, and claims therein found allowable, the corresponding method-of-use claims will be rejoined for further examination.

. . . .

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect species/subgenera (as follows) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable:

In the event that Group 1 is chosen for initial examination, election is required of each of the following:

a) one of the following: (i) a compound *per se* (in accordance with claim 1) or (ii) a composition *per se* (in accordance with claim 19);

b) in the event that a compound is elected, election is required of a specific and fully defined compound (which can be described without the use of the term "comprising" or "consisting essentially of");

c) in the event that a composition is elected (in accordance with claim 19), election is required of a specific and fully defined composition in which all ingredients are fully accounted for;

. . . .

In the event that Group 2 is chosen for initial examination, election is required of a specific and fully defined compound.

. . . .

In the event that Group 3 is chosen for initial examination, election is required of each of the following:

a) one of the following: (i) a compound *per se* (in accordance with claim 11) or (ii) a composition *per se* (in accordance with claim 26);

b) in the event that a compound is elected, election is required of a specific and fully defined compound (which can be described without the use of the term "comprising" or "consisting essentially of");

c) in the event that a composition is elected (in accordance with claim 26), election is required of a specific and fully defined composition in which all ingredients are fully accounted for;

. . . .

In the event that Group 4 is chosen for initial examination, election is required of each of the following

a) one of the following: (i) the target medicament is a compound *per se* or (ii) the target medicament is a composition;

b) in the event that the target medicament is a compound *per se*, election is required of a specific and fully defined compound;

c) in the event that the target medicament is a composition, election is required of a specific and fully defined composition;

. . . .

In the event that Group 6 is chosen for initial examination, election is required of each of the following:

a) one of the following: (i) the target medicament is a compound *per se* or (ii) the target medicament is a composition;

b) in the event that the target medicament is a compound *per se*, election is required of a specific and fully defined compound;

c) in the event that the target medicament is a composition, election is required of a specific and fully defined composition;

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that

this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. ∋103 of the other invention.

✦

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

D. Lukton

DAVID LUKTON, PH.D.
PRIMARY EXAMINER

10-530016

Application No.:

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [x] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked –up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other:

Applicant Must Provide:

- [x] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [x] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [x] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g).

For questions regarding compliance to these requirements, please contact:

- For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
- For CRF Submission Help, call (703) 308-4212
- For PatentIn software Program Support:
  - HELP DESK: (703) 739-8559, ext 508, M-F, 8 AM to 5 PM EST except holidays
  - Email: PATIN21HELP@uspto.gov
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